UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION
PREVENTION

April 30, 2020

MEMORANDUM

Subject: Efficacy Review for Firebird F-130, EPA Reg. No. 42182-9; DB Barcode: D455274; E-Sub #: 44017; Submission #: 1042708.

From: Ibrahim Laniyan, Ph.D.
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Thru: Cesar E. Cordero, Acting Efficacy Team Leader
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To: Jacqueline Hardy RM 34 / Lorena Rivas
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Applicant: Microban Products Company
11400 Vanstory Drive
Huntersville, NC 28078

Formulation from the Label:

Active Ingredient	% by wt.
Alkyl dimethyl benzyl ammonium chloride ($50\%C_{14}$, $40\%C_{12}$, $10\%C_{16}$)	0.276 %
Didecyl dimethyl ammonium chloride	0.104 %
Octyl decyl dimethyl ammonium chloride	0.207 %
Dioctyl dimethyl ammonium chloride	0.104 %
Ethanol	68.610 %
Other Ingredients	30.699 %
Total	100.000 %

I. BACKGROUND

Product Description (as packaged, as applied): Ready to Use liquid

Submission type: Label amendment requiring data review

Currently registered efficacy claim(s): Hospital disinfectant, 24 Hour Residual disinfectant, Soft Surface spot Sanitizer, Hard surface mildewstat, Fabric mildewstat, Cleaner, and Deodorizer.

Requested action(s):
1) Disinfection claims against two additional bacteria
2) 24-hour residual/continuous disinfection claims against 4 additional bacteria

Documents considered in this review:

- Letter from applicant to EPA dated (EPA form 8570-4) dated October 30, 2019
- Application for Pesticide (EPA form 8570-1) dated October 30, 2019
- Data Matrix (EPA Form 8570-35) dated October 30, 2019
- 6 efficacy studies (MRID nos. 509746-01 - 509746-06)
- Proposed label Version 103019 PRIA AMEND

II. PROPOSED USE DIRECTIONS

Sanitizing Directions

Hold container 6”- 8” from surface and spray until thoroughly wet[treated].
To Sanitize Hard Non-porous surfaces: Let stand 10 seconds. Wipe clean with a [damp] cloth [or sponge] [or paper towel]. Pre-clean heavily soiled surfaces. [Kills [effective against] [99.9% of] {Insert non-food contact sanitization bacteria from Table C}.]
To [spot] Sanitize Soft [Fabric] surfaces: Let stand for 10 seconds. Let air dry. [For difficult odors, repeat application] [Kills [effective against] [99.9% of] {Insert soft surface sanitization bacteria from Table D}.]

Disinfecting Directions

TO DISINFECT Hard, non-porous surfaces: Hold container 6”-8” from surface and spray until thoroughly wet.
{or}
TO DISINFECT Hard, non-porous surfaces: Hold container 6”-8” from surface and spray. Ensure even coverage and thorough wetness.
{one of the following statements will be used, with only the corresponding organisms listed on container label based on contact time} [Bacteria , [yeast] and Cold and Flu Viruses§:] Let stand [for] 60 seconds [-or- 1 minute]
{or}
[Bacteria, Enveloped viruses, [Rotavirus,][Fungi,][Yeast,][and Mold and Mildew] [Mycobacteria (TB)]:] Let stand [for] 3 minutes.
{or}
[Bacteria, Viruses‡,[Mycobacteria (TB)] [and] Fungi , [Yeast,] [and mold & mildew]:] Let stand [for] 5 minutes.
{in conjunction with:} [Wipe with a lint free microfiber cleaning cloth] [to avoid lint or paper towel residue]. Preclean heavily soiled surfaces. [Kills] [effective against] [99.9% of] {Insert appropriate organisms from Table A based on 1, 3, or 5 minute contact time.}
[And][/][Or]
[Residual Disinfection [-or-Continuous Disinfection Directions]
For Residual Disinfection [-or-Continuous Disinfection] on hard non-porous surfaces for 24 Hours: Hold container 6”-8” from surface and spray. Ensure [even][uniform] coverage [distribution] and thorough wetness. Allow to air dry. See Continuous Disinfection table for contact time.

Preclean heavily soiled surfaces. [Kills 99.999% of][Effective Against] [bacteria] {insert bacteria from Table B}] [Provides residual disinfecting activity for up to 24 hours.]
[Product [residue] can be removed by soap and water [or by re-application of the product].] [Periodic cleaning with soap and water is optional.]
Use of this product [for Residual Disinfection [-or- Continuous Disinfection]] should not alter standard cleaning and disinfection practices. If the treated surface is cleaned, reapplication of [this] product is necessary for Residual Disinfection [-or- Continuous Disinfection].

Mildew Fungistatic Directions

TO PREVENT MOLD [AND MILDEW] [growth]:
[Fabric[Soft Surface] Mildewstat] On [cotton and polyester [nonwoven]] Fabrics:
[To inhibit mold and mildew growth]: Apply to fabric surface until wet [do not saturate]. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against Aspergillus brasiliensis [mildew] and Penicillium variable.] Pre-clean heavily soiled surfaces.
[Hard Surface Mildewstat] On hard surfaces:
[To inhibit mold and mildew growth]: Thoroughly wet surface. Allow to air dry. Repeat [application] every 7 days to inhibit mold [and mildew] growth. [Effective against Aspergillus brasiliensis [mildew]] Pre-clean heavily soiled surfaces.

III. DESCRIPTION OF THE EFFICACY DATA

1. MRID 509746-01, "AOAC Germicidal Spray Method. Organisms: Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Completion date - October 2, 2019. Project No. A27474.

This study was conducted against Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751). Two lots (190214-001 and 190214-002) of the product, Firebird F-130, were tested using Accuratus Lab Services protocol # SRC90122917.GS.1 (copy provided). All product lots were tested according to the LCL policy. The product was received ready-to-use trigger spray. Testing was conducted in the presence of 5% soil load. Ten (10) sterile glass slide carriers per product lot were inoculated with 0.01 ml of a 48.25 hours old culture of the test organism. Carriers were dried 35 minutes at 36.1-36.2°C and 47.4-48.1% relative humidity until visibly dry. Carriers were used in the test procedure within 2 hours of drying. Following drying, carriers were sprayed with 6 sprays of the test substance at a distance of approximately 6-8 inches at ~45° angle. After the 55-second exposure period at room at room temperature (19°C) and 24% relative humidity), the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth+ 0.14% Lecithin + 1.0% Tween 80) using sterile forceps. All plates and subculture tubes were incubated under 36.0°C for 49.25 hours. Subculture were examination for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Cefazolin, Ampicillin, and Ampicillin/Sulbactam.

2. MRID 509746-02, "AOAC Germicidal Spray Method. Organisms: Multi-drug Resistant *Enterococcus faecium* (ATCC 51559)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Completion date - October 2, 2019. Project No. A27473.

This study was conducted against Multi-drug Resistant *Enterococcus faecium* (ATCC 51559). Two lots (Lot 190214-001 and Lot 190214-002) of the product, Firebird F-130, were tested using Accuratus Lab Services protocol no. SRC90122917.GS.2 (copy provided). All product lots were tested according to the LCL policy. The

product was received ready-to-use trigger spray. Testing was conducted in the presence of 5% soil load. Ten (10) glass slide carriers per product lot were inoculated with 0.01 ml of a 50 hours old culture of the test organism then dried at 27.0-27.1°C for 36 minutes and 65-66% relative humidity (RH) until visibly dried. Carriers were used in the test procedure within 2 hours of drying. Carrier were sprayed with 6 sprays of the test substance at a distance of approximately 6-8 inches. After the 55-second exposure periods at room temperature (19°C) and 24% relative humidity), the excess test substance was allowed to drain off the carrier prior to aseptically transferring to individual test tubes containing 20 mL of neutralizer/subculture medium (Letheen Broth + 0.5% Lecithin + 2.0% Tween 80) using sterile forceps. All subcultures were incubated for 46.5 hours at 36°C. Following incubation, the subcultures were visually examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Ampicillin, Penicillin, Vancomycin, Gentamicin (tobramycin and amikacin).

3. MRID 509746-03, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organisms: Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605)", for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - October 21, 2019. Project No. A27565.

This study was conducted against Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605). Two lots (Lot Nos. 190214-001 and 190214-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90122917.GUST.1.PROP, EPA Protocol 42182-PA-3 (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (4 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered at 19.4-20°C, 46-47% relative humidity in a humidity controlled chamber for 30 minutes, or until visually dry up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.1°C for 30 minutes at 50.8% RH, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (20°C) and room humidity (52-54%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 20.0°C and 50-55% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes at 20°C and 53% relative humidity, the carriers were transferred to 10 ml of Letheen Broth + 0.28% Lecithin + 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48 hours at 36.0°C then were stored at 2-8°C for 2-3 days. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

Note: Protocol deviation and amendments were reviewed.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Ampicillin/Sulbactam, Cefepime, Cefazolin, Ceftazidime, Ceftriaxone, Ciprofloxacin, Gentamicin, Levofloxacin, Piperacillin/Tazo, Trimethoprim/Sulfa, Meropenem

4. MRID 509746-04, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organism: Multi-drug Resistant *Enterobacter aerogenes* (ATCC

29751)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - October 21, 2019. Project No. A28264.

This study was conducted against Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751). Two lots (Lot Nos. 190214-001 and 190214-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90122917.CUST.2.PROP (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (4 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered at 22.0-22.2°C, 48% relative humidity in a humidity controlled chamber until visually dry, up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.0-36.1°C for 30 minutes at 50.1% relative humidity, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (20°C) and room humidity (52-54%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 22.0°C and 48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0 g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes at 20°C and 47% relative humidity, the carriers were transferred to 10 ml of Letheen Broth + 0.28% Lecithin + 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48.5-52 hours at 36.0°C then were stored at 2-8°C for 2-3 days. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Cefazolin

5. MRID 509746-05, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organism: Multi-drug Resistant (MDR) *Enterococcus faecium* (ATCC 51559)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - October 21, 2019. Project No. A28324.

This study was conducted against Multi-drug Resistant (MDR) E*nterococcus faecium* (ATCC 51559). Two lots (Lot Nos. 190214-001 and 190214-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90122917.CUST.3.PROP (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (4 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered 30 minutes, at 21.1-21.5°C, 48% relative humidity in a humidity controlled chamber until visually dry, up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.0-36.1°C for 30 minutes at 50.1% relative humidity, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (20°C) and room humidity (52-54%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 22.0°C and 48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0 g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 4.5 minutes at 20°C and 50% relative humidity, the carriers were transferred to 10 ml of Letheen Broth + 0.28% Lecithin + 2.0% Tween

80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48.5-49.5 hours at 36.0°C then were stored at 2-8°C for 2-3 days. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Ampicillin, Penicillin, Vancomycin, Gentamicin (tobramycin and amikacin).

6. MRID 509746-06, "Residual Activity of Dried Chemical Residues on Hard Nonporous Surfaces with Exposure and Wear Activity. Organism: New Delhi Metallo-beta-lactamase-1 (NDM-1) producing Klebsiella pneumoniae (ATCC BAA-2146)" for Firebird F-130; by Matthew Sathe. Study conducted at Accuratus Lab Services; Study completion date - October 22, 2019. Project No. A28532.

This study was conducted against New Delhi Metallo-beta-lactamase-1 (NDM-1) producing *Klebsiella pneumoniae* (ATCC BAA-2146). Two lots (Lot Nos. 190214-001 and 190214-002) of the product, Firebird F-130, were tested according to Accuratus Lab Services Protocol No. SRC90091619.CUST.PROP (copy provided). The product was received ready-to-use spray. Testing was conducted in the presence of 5% soil load. Four one-inch square glass carriers per organism per product lot were treated (4 sprays with the product from a distance of 6-8 inches at 45° angle) and allowed to dry uncovered 30 minutes, at 22.0-22.9°C, 45-48% relative humidity in a humidity controlled chamber until visually dry, up to 1 hour. Each carrier was inoculated with a 10 µL aliquot of each 48-54 hour old culture suspensions and spread to within 1/8 inch of the carrier edges. Carriers were dried at 36.0-36.1°C for 30 minutes at 50.8% relative humidity, or until visually dry. Immediately following drying, a series of 12 wear cycles (alternate 6 dry and 6 wet cycles) and 11 re-inoculation (with 10 µL of 18-24 hour old cultures) cycles to support a 24 hour residual disinfection claim. Abrasions were conducted at room temperature (20°C) and room humidity (46-49%), with measurements taken and recorded daily. Between abrasions, carriers were returned to a humidity controlled chamber uncovered at 22.0°C and 48% relative humidity. The weights of the fully assembled abrasion boats were recorded, prior to initiation of the wear and re-inoculation regimen and all weights equaled 1084±1.0 g. The abrasion tester was set to a speed of 2.5 for a total surface contact time of approximately 8-10 seconds, for one complete abrasion cycle. Each abrasion cycle in this test equaled four (4) passes, one pass to the left and one return pass to the right followed by another pass to the left and another return pass to the right. The wet abrasion (wear #12) was followed by a final inoculation of 10 µL of a 18-24 hour old culture. After 5 minutes at 20°C and 50% relative humidity, the carriers were transferred to 10 ml of Letheen Broth + 0.28% Lecithin + 2.0% Tween 80, sonicated for 20±2 seconds, and then sufficiently vortexed. Serial dilutions were prepared in Butterfield buffer, and plated in duplicate within 30 minutes of neutralizing. All plates were incubated for 48.25-51 hours at 36.0°C then were stored at 2-8°C for 2-3 days. Colonies then were counted. Controls included initial inoculation carrier, reinoculation carrier, sterility, purity, and neutralization.

Notes: Antibiotic sensitivity testing was performed using a representative culture from the day of testing and verified the antibiotic resistance pattern of the test organism. It is found to be resistant to Amikacin, Ampicillin, Ampicillin/Sulbactam, Cefazolin, Cefepime, Ceftazidime, Ceftriaxone, Ciprofloxacin, Gentamicin, Imipenem, Levofloxacin, Piperacillin/Tazo, Tobramycin, Trimethoprim/Sulfa, Meropenem, Ertapenem.

IV. STUDY RESULTS

MRID Number	Organism	No. Carriers Exhibiting Growth/Total		Carrier Population (log_{10})
		190214-001	190214-002	
RTU Trigger spray – 5% serum – 55 seconds contact time – Ambient room temperature				

509746-01	Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751)	0/10	0/10	4.79
509746-02	Multi-drug Resistant *Enterococcus faecium* (ATCC 51559)	0/10	0/10	4.95

MRID #	**)Organism**	**Lot No.**	**CFU/Carrier Average Log_{10}**	**Percent Reduction**	**Carrier Population (log_{10} CFU/Carrier)**	
					Non-Abrasion	**Abrasion**
509746-03	Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605)	190214-001 190214-002	<1.08 <1.00	>99.999% >99.999%	6.46	6.67
509746-04	Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751)	190214-001 190214-002	<1.00 <1.00	>99.999% >99.999%	6.39	6.36
509746-05	Multi-drug Resistant (MDR) *Enterococcus faecium* (ATCC 51559)	190214-001 190214-002	<1.00 <1.00	>99.999% >99.999%	6.26	6.27
509746-06	New Delhi Metallo-beta-lactamase-1 (NDM-1) producing *Klebsiella pneumoniae* (ATCC BAA-2146)	190214-001 190214-002	<1.15 <1.18	>99.999% >99.999%	6.59	6.59

V. CONCLUSIONS

MRID	**Claim**	**Surface Type**	**Application Method(s) and Dilution**	**Contact Time**	**Soil load**	**Diluent**	**Organism(s)**	**Data support Label Claims?**
509746-01 **509746-02**	**Disinfectant Bactericidal**	Hard, non-porous surfaces	RTU Spray	55 sec.	5% FBS	No	Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751) Multi-drug Resistant *Enterococcus faecium* (ATCC 51559)	**Yes**
509746-03 **509746-04** **509746-05** **509746-06**	**Residual Bactericidal Disinfection**	Hard, non-porous surfaces	RTU Spray	4.5 min.	5% FBS	No	Multi-drug Resistant (MDR) *Acinetobacter baumannii* (ATCC BAA-1605) Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751) Multi-drug Resistant (MDR)	**Yes**

							Enterococcus faecium (ATCC 51559) New Delhi Metallo-beta-lactamase-1 (NDM-1) producing *Klebsiella pneumoniae* (ATCC BAA-2146)	

VI. LABEL COMMENTS

Label Version 103019 PRIA AMEND

1. The proposed label claims are **acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-9), as a disinfectant with bactericidal activity on hard, non-porous visibly clean surfaces, at room temperature, for a 1-minute contact time. These claims are supported by the applicant's data:

- Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751)
- Multi-drug Resistant *Enterococcus faecium* (ATCC 51559)

2. The proposed label claims **are acceptable** regarding the use of the product, Firebird F-130 (EPA File No. 42182-9), as a disinfectant with 24-hour residual disinfection activity for use on hard, non-porous surfaces against the following microorganisms in the presence of 5% organic soil, at room temperature, for a 5-minute contact time after drying onto surfaces. These claims are supported by the applicant's data:

- Multi-drug Resistant (MDR)
- *Acinetobacter baumannii* (ATCC BAA-1605)
- Multi-drug Resistant *Enterobacter aerogenes* (ATCC 29751)
- Multi-drug Resistant (MDR)
- *Enterococcus faecium* (ATCC 51559)
- New Delhi Metallo-beta-lactamase-1 (NDM-1) producing
- *Klebsiella pneumoniae* (ATCC BAA-2146)

3. Make the following changes to the proposed label:

- Add to direction of use, cleaning instruction necessary for pre-cleaning of visibly soiled surfaces.
- Replace all heavily soiled with “visibly soiled”
- Throughout the “DIRECTIONS FOR USE” (Starting on page 2 of the label) replace the statement “Let stand for X seconds/minutes” with “Allow surface to remain visibly wet for X seconds/minutes” to ensure proper contact time application.
- On page 7, remove “Eradicate” because it is misleading.
- On page 9, remove “Reduces [nosocomial][hospital acquired][hospital borne] bacteria transmitted via contaminated surfaces” because transmission of bacteria has not been studied.
- On page 9, delete or clarify the terms “Destroy”, “Wipes out”, and “Eliminates” with the appropriate removal percentage.
- On page 9, delete the descriptors “Only” and “first” as these may/are likely misleading and/or inaccurate from the claim: “[Breakthrough][Innovative][Revolutionary**[Only][first]]**[disinfectant][disinfecting] [technology][[approach] [method] [process] [solution] [product] that [is][provides]{insert any of the following bullet points from this section}”
- On page 11, replace “lightly soiled” with “visibly clean”